

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
Norfolk, Division

IN RE: ZETIA (EZETIMIBE) :  
ANTITRUST LITIGATION :  
 :  
 : Civil Action No. 2:18-md-2836  
 :  
This Document Relates to: :  
All Cases :

MEMORANDUM OPINION AND ORDER

In this multidistrict litigation, Plaintiffs allege that Defendants Merck<sup>1</sup> and Glenmark<sup>2</sup> (collectively "Defendants") conspired to delay generic competition for the branded cholesterol medication Zetia by artificially prolonging its patent protection. The pretrial motion now before the court is Plaintiffs' motion *in limine* No. 15, which seeks to exclude Defendants' claimed procompetitive justifications that, Plaintiffs assert, are contrary to law. (ECF No. 1806, at 2). The court held a final pretrial conference on March 22 and 23, 2023, at which the parties presented arguments on several pending pretrial matters, including this motion *in limine*. After reviewing the briefing and hearing the parties' arguments at the

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<sup>1</sup> "Merck" consists of Merck & Co., Inc.; Merck Sharp & Dohme Corp.; Schering-Plough Corp.; Schering Corp.; and MSP Singapore Co. LLC.

<sup>2</sup> "Glenmark" consists of Glenmark Pharmaceuticals Limited and Glenmark Pharmaceuticals Inc., USA, the latter incorrectly identified as Glenmark Generics Inc., USA.

March 23 final pretrial conference, I conclude that Defendants' claimed procompetitive justifications are not contrary to law and therefore should not be excluded. Accordingly, as set out in detail below, Plaintiffs' motion *in limine* No. 15 is DENIED.

## I. BACKGROUND

The allegations underlying this multidistrict litigation have been set forth in previous opinions.<sup>3</sup> A summary of the facts relevant to this motion is set forth below.

### A. Underlying Merck-Glenmark Settlement Agreement

On May 10, 2010,<sup>4</sup> Merck and Glenmark signed a settlement agreement resolving all outstanding claims<sup>5</sup> in the patent

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<sup>3</sup> In re Zetia (Ezetimibe) Antitrust Litig., No. 2:18-md-2836, 2019 WL 6122017, at \*1-3 (E.D. Va. Oct. 15, 2019), R. & R. adopted as modified, 2019 WL 6977405 (E.D. Va. Dec. 20, 2019); In re Zetia (Ezetimibe) Antitrust Litig., No. 2:18-md-2836, 2019 WL 1397228, at \*1-10 (E.D. Va. Feb. 6, 2019), R. & R. adopted as modified, 400 F. Supp. 3d 418 (E.D. Va. 2019).

<sup>4</sup> At the time of its settlement with Glenmark, Merck was also suing Mylan, another generic drug company which was the first ANDA filer for generic Vytorin<sup>4</sup> and the second ANDA filer for generic Zetia. Merck Summ. J. Mem. ¶¶ 38-47 (ECF No. 1085, at 19-22); DPPs' Am. Compl. ¶¶ 221-23 (ECF No. 128, at 67-68). Mylan similarly claimed that the RE'721 Patent was invalid or unenforceable. Merck Summ. J. Mem. ¶ 38 (ECF No. 1085, at 19-20); DPPs' Am. Compl. ¶ 224 (ECF No. 128, at 68).

<sup>5</sup> Glenmark stipulated to infringement but counterclaimed that the RE'721 Patent was either invalid or unenforceable on several bases. Id. ¶ 33 (ECF No. 1083-18, at 19-20). The generic manufacturer defended based on improper reissue, obviousness-type double patenting ("ODP"), failure to name an inventor, and inequitable conduct committed during the patent-term extension period. Id. ¶ 52 (ECF No. 1083-18, at 29-30).

Eventually Glenmark filed two motions for partial summary judgment on its defenses related to reissue and ODP. Id. ¶¶ 48-49 (ECF No. 1083-18, at 26-29). The district court granted Glenmark's motion on its improper reissue defense but denied the other motion. Id. The Federal

litigation underlying this MDL. Sett. Agr. (ECF No. 398-21). Under the terms of the Agreement, Glenmark could launch its generic ezetimibe product on December 12, 2016. Id. § 5.4 (ECF No. 398-21, at 13). Merck also agreed to reimburse Glenmark for up to \$9 million in attorneys' fees. Merck Mem. Supp. Mot. Summ. J. ("Merck Summ. J. Mem.") ¶ 35 (ECF No. 1085, at 18-19). Merck had incurred \$21 million in legal fees up to that point. Id.

The Settlement Agreement granted Glenmark an exclusive right to market "generic ezetimibe." Sett. Agr. § 5.3 (ECF No. 398-21, at 12-13). However, "generic ezetimibe" is defined in the Settlement Agreement as

a drug product containing ezetimibe as its sole active ingredient (a) that refers to the Approved Zetia Product as the reference-listed drug . . . or (b) that is sold pursuant to NDA No. 21-445 but is not sold under the trademark Zetia® or another trademark or trade name of Schering, MSP or their Affiliates.

Id. § 1.14 (ECF No. 398-21, at 6) (emphasis added). Purchasers contend that this definition is a no-AG Agreement granting Glenmark an exclusive license over generic ezetimibe. Pls.' Opp'n Defs.' Mots. Summ. J. ("Pls.' Summ. J. Opp'n") ¶¶ 7-8 (ECF No. 1156, at 25-26). Defendants contend that this definition is a "limited

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Circuit later "effectively overturned" United States District Judge Jose L. Linares's reasoning on the improper reissue decision. See DPPs' Am. Compl. ¶ 228 (ECF No. 128, at 69). As part of their eventual settlement, Merck and Glenmark jointly moved to vacate the summary judgment order, which Judge Linares granted. Id. ¶ 180 (ECF No. 128, at 58).

exclusive license." Merck Summ. J. Mem. (ECF No. 1085, at 29).

**C. The Present Motion**

On January 17, 2023, Purchasers moved to exclude Defendants' claimed procompetitive justifications for the challenged restraint on competition that, Purchasers contend, are contrary to law. (ECF No. 1806, at 2). Purchasers specifically take issue with the following defenses:

(a) that the payment was justified by Defendants' "risk aversion" or "litigation uncertainty"; (b) that purported 'early entry' benefitted consumers; (c) that patent settlements are generally beneficial; (d) that patents generally benefit society; or (e) that supracompetitive prices were necessary to recoup Merck's investment in Zetia and to incentivize future investment in developing new drugs.<sup>6</sup>

Mem. Supp. Mots. Limine Nos. 11-16 ("Pls.' Mem.") (ECF No. 1809, at 13-14).

On January 30, 2023, Defendants opposed Plaintiffs' motion. (ECF No. 1910). They argue that their procompetitive justifications are cognizable under established law. Defs.' Opp'n

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<sup>6</sup> Purchasers acknowledge that their motion is more directed at argument, jury instructions, and the verdict form rather than the underlying evidence, which they agree will be likely be admitted for other purposes at trial, such as proving the existence of a reverse payment at Step 1 of the rule of reason. March 23 Hr'g Tr. 47:11-12 (ECF No. 2032) ("I don't think that much of this is a limitation on evidence . . . ."); id. at 47:3-5 ("So the evidence will come in, but now the question is what people are allowed to do with it . . . ."); id. at 55:9-15 ("This motion is not about specific evidence . . . . this motion is about the arguments that the defendant[s] are allowed to make in order to justify this payment."); id. at 75:22-23 ("It's the argument that we're dealing with, . . . it's not particular evidence . . . .").

Pls.' Mots. Limine Nos. 15-16 ("Defs.' Opp'n") (ECF No. 1910, at 6-25).

## II. STANDARD OF REVIEW

The purpose of a motion *in limine* is "to allow a court to rule on evidentiary issues in advance of trial in order to avoid delay, ensure an even-handed and expeditious trial, and focus the issues the jury will consider." United States v. Verges, No. 1:13cr222, 2014 WL 559573, at \*3 (E.D. Va. Feb. 12, 2014). However, a motion *in limine* to exclude evidence "should be granted only when the evidence is clearly inadmissible on all potential grounds." Id.

Rule 401 of the Federal Rules of Evidence governs the relevance of evidence. Under Rule 401, relevance is established if the evidence "has a tendency to make a fact more or less probable than it would be without the evidence," and "the fact is of consequence in determining the action." Fed. R. Evid. 401. "Relevance is typically a low bar to the admissibility of evidence, even though other Federal Rules of Evidence may otherwise limit such admissibility." Jones v. Ford Motor Co., 204 Fed. App'x 280, 283 (4th Cir. 2006) (citing Fed. R. Evid. 403, 404).

One such rule otherwise limiting the admissibility of relevant evidence is Rule 403. Rule 403 allows the Court to "exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair

prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. Application of Rule 403 presupposes that the subject evidence is relevant. See Fed. R. Evid. 401. The task is to "balanc[e] the probative value of and need for the evidence against the harm likely to result from its admission." Fed. R. Evid. 403 advisory committee's note. At bottom, admissibility is within the trial court's discretion. United States v. Melton, 970 F.2d 1328, 1336 (4th Cir. 1992) (citing United States v. Simpson, 910 F.2d 154, 157 (4th Cir. 1990)).

### III. ANALYSIS

After reviewing the record, I find that Defendants' claimed procompetitive effects defenses are not contrary to law. Although the parties hotly contest whether these defenses are factually sufficient for Defendants to avoid antitrust liability, that is a question for the jury to decide at trial. The court will not take that issue away from the jury absent a legal deficiency in the proffered defenses, which is not the case here. Accordingly, for the reasons set forth in below, the court DENIES Plaintiffs' motion *in limine* No. 15, (ECF No. 1806, at 2).

#### **A. Defendants' Procompetitive Effects Defenses Are Not Contrary to Law.**

The rule of reason, applied to reverse payment cases by the Supreme Court in Federal Trade Commission v. Actavis, 570 U.S. 136

(2013), is a three-step, burden-shifting framework for analyzing claims under the Sherman Act. "[C]ourts analyzing reverse payment agreements have consistently applied" the rule of reason to determine whether a violation of the antitrust laws occurred. See In re Zetia (Ezetimibe) Antitrust Litig., No. 2:18-md-2836, 2019 WL 1397228, at \*20 (E.D. Va. Feb. 6, 2019), R. & R. adopted as modified by 400 F. Supp. 3d 418 (E.D. Va. Aug. 9, 2019). In a reverse payment case, at Step 1 of the analysis, antitrust plaintiffs have the burden to show that a payment was made from the patentholder to the patent challenger to avoid the risk of competition. Actavis, 570 U.S. at 154-55. If the plaintiffs can show the existence of a "large and unjustified" payment, an inference arises that the payment was made to prevent the risk of competition. Id. at 157-58. If the plaintiffs satisfy their Step 1 burden, the analysis turns to Step 2, where the antitrust defendants have the burden to show a procompetitive justification for the challenged restraint on competition. Ohio v. Am. Express Co., 138 S. Ct. 2274, 2284 (2018). Upon such a showing, the analysis moves to Step 3, where the plaintiffs have the burden to rebut the justifications offered, and prove the restraint on competition was anticompetitive and violated the Sherman Act. King Drug Co. of Florence v. Smithkline Beecham Corp., 791 F.3d 388, 412 (3d Cir. 2015).

At the heart of the dispute in this motion is a fundamental

disagreement about Step 2 of the rule of reason analysis. Purchasers' read Actavis and its progeny to hold that the "challenged restraint" for which justification must be shown is "the challenged term" or "reverse payment" in the settlement agreement -- which, they contend, is the no-AG provision. Pls.' Mem. Supp. Mots. Limine Nos. 11-16 ("Pls.' Mem.") (ECF No. 1809, at 14 n.26). In other words, Purchasers believe that Defendants' burden at Step 2 is to produce a procompetitive justification for the reverse payment specifically as opposed to the Settlement Agreement as a whole. Id. at 14. Purchasers' claim that the justifications Defendants have offered thus far only relate to the Settlement Agreement as a whole and are not related to -- or sufficient justification for -- the reverse payment itself. Id. at 16-22.

In support of their position, Purchasers point to the statement in Actavis that "[a]n antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason." Id. at 14 n.26, 17 (citing Actavis, 570 U.S. at 156). They claim that Actavis' focus on the "challenged term" was consistent with the Supreme Court's reasoning in NCAA v. Board of Regents, 468 U.S. 85 (1984), in which the Court found that the "specific restraints" at issue did not serve the procompetitive goal offered

by the NCAA. Id. at 15 (citing NCAA, 468 U.S. at 116-17). Purchasers also cite to In re K-Dur Antitrust Litig., 686 F.3d 197 (3d Cir. 2012) and King Drug. Co. of Florence, Inc. v. Cephalon, Inc., 88 F. Supp. 3d 402 (E.D. Pa. 2015), two reverse payment cases which they argue hold that the defendant must prove that the reverse payment itself is justified. Id. at 14 n.26 (citing In re K-Dur, 686 F.3d at 218; King Drug, 88 F. Supp. 3d at 416).

Defendants have a different view. They read Actavis to hold that the "challenged restraint" for which justification must be shown is the entire Settlement Agreement. Defs.' Opp'n Pls.' Mots. Limine Nos. 15-16 ("Defs.' Opp'n") (ECF No. 1910, at 7). In other words, Defendants believe that their burden at Step 2 is to show a procompetitive justification for the Settlement Agreement as a whole rather than the no-AG provision specifically, a burden which -- they allege -- will be satisfied by the offered justifications Purchasers seek to exclude, among others. Id. at 8-25.

In support of their position, Defendants cite In re Glumetza Antitrust Litig., 2021 WL 3773621, at \*8 (N.D. Cal. Aug. 25, 2021), another case with an alleged no-AG provision. Id. at 7. There -- relying on the same language in Actavis that Purchasers now cite -- the plaintiffs argued that "a defendant may not claim procompetitive justification for the settlement as a whole, and instead, as part of the rule-of-reason analysis, must demonstrate the no-AG provision had procompetitive effects." In re Glumetza,

2021 WL 3773621, at \*8 (cleaned up). The court disagreed, concluding that "the Supreme Court's language, in context, contemplated a broader review of the agreement than solely the no-AG term in isolation." Id.

Defendants also rely on In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. 14-md-02503, 2018 WL 734655, at \*4 (D. Mass. Feb. 6, 2018). Defs.' Opp'n (ECF No. 1910, at 7). Like in In re Glumetza, the plaintiffs in In re Solodyn argued that the defendants "proffered justifications focus, improperly, upon the settlement agreements as a whole, rather than justifying the payment itself." In re Solodyn, 2018 WL 734655, at \*4. The court "decline[d] to take such a narrow view, such that the payment would be divorced from its business context." Id. The court in In re Loestrin 24 Fe Antitrust Litig., 433 F. Supp. 3d 274 (D.R.I. 2019) -- which Defendants also cite, Defs.' Mem. (ECF No. 1910, at 7) -- followed the District of Massachusetts' holding in In re Solodyn.

Having reviewed the cases cited by the parties and considered the arguments on both sides, I agree with Defendants' reading of Actavis and conclude that, in this case, the "challenged restraint" cannot be separated from the Settlement Agreement as a whole. The specific, no-AG provision Purchasers allege to be a term of that agreement is the challenged provision which Purchasers claim violates the antitrust laws. But the restraint on competition for

ezetimibe for which they seek damages flows from entire agreement -- not from that term exclusively. Put another way, it is the Settlement Agreement as a whole that ended the Merck-Glenmark litigation, thereby eliminating Glenmark's challenge to Merck's ezetimibe patent and keeping the generic manufacturer off the market. The no-AG provision -- if proven -- was not negotiated in isolation from the rest of the agreement, and consequently it cannot be separated from the procompetitive or anticompetitive effects of the Settlement Agreement as a whole. As such, Defendants are entitled to argue that the entire Settlement Agreement was procompetitive, and are entitled to rely on procompetitive justifications for the Agreement, including the negotiated early entry date in December 2016, and the advantages of certainty that come from settlements generally.

At the March 23 conference, Purchasers attempted to distinguish the cases cited by Defendants. They claimed that this court should not follow In re Solodyn because the judge in that case misquoted Actavis. March 23 Hr'g Tr. 81:20-82:11 (ECF No. 2032). This error, Purchasers argued, renders In re Loestrin inapplicable as well because that case followed In re Solodyn. Id. at 82:12-14. However, I am not persuaded that the quote described was a "mistake" as Purchasers assert, rather than an intentional statement indicating a reading of Actavis aligning with Defendants' view -- and that of other courts. As to In re

Glumetza, Purchasers contended that the reverse payment at issue in that case included marketing arrangements, which are not present here. Id. at 82:18-83:2. However, I do not find that to be a persuasive or material distinction.

Another problem with Purchasers' position is that it presumes both the existence and effect of the no-AG provision alleged. Purchasers are asking the court to exclude argument at Step 2 by arguing that the "challenged restraint" is not the settlement as a whole but a discrete period of delay which their experts claim arose from the reverse payment.<sup>7</sup> But the jury has not yet determined whether there was a reverse payment at all. Unlike Actavis, which involved a simple cash payment, the alleged reverse payment here is a specific term -- the alleged no-AG provision -- encompassed in a broader settlement agreement. Moreover, Defendants hotly contest the meaning and effect of that term and Purchasers have not moved for summary judgment on the issue. Given that the existence of the no-AG provision and its related discrete period of delay are both issues for trial, I do not find that they can be separated from the Settlement Agreement at Step 2 of the rule of reason. The court will not limit Defendants procompetitive

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<sup>7</sup> The court's summary judgment ruling -- which assumed resolution of contested facts in Purchasers' favor -- described this hypothetical period as the time between the actual entry date and a competitively balanced entry date without a reverse payment. In re Zetia (Ezetimibe) Antitrust Litig., No. 2:18-md-2836, 2023 WL 1880038, at \*8 (E.D. Va. Feb. 10, 2023).

justifications -- at this stage -- by requiring they concede the existence of Purchasers as yet unproven allegation of a no-AG provision.

This issue was recently considered by United States District Judge Edward M. Chen Judge when confronted with a similar motion *in limine* in another antitrust case pending in the Northern District of California -- which involves many of the same lawyers appearing in this case. See Order Re Trial Structure & Mots. Limine ("HIV Order"), In re HIV Antitrust Litig., 19-cv-02573-EMC (N.D. Cal. Mar. 19, 2023) (ECF No. 2005-1, at 15-16). In that case, the plaintiffs argued that, "at step two, Defendants can only talk about the procompetitive effects of the restraint at issue in [the] case -- i.e., the reverse payment -- and cannot talk about the procompetitive effects of the broader settlement agreement of which the reverse payment is a part." Id. at 16. Judge Chen concluded that position was "too restrictive." Id. Citing In re Glumetza, he reasoned that if the generic manufacturer did agree to delay entry into the market, "then the finder of fact must consider what benefits [the generic manufacturer] received in exchange," which would include "not only the reverse payment (as alleged by Plaintiffs) but also [a] broad license to use FTC [products] (as alleged by Defendants)." Id. In other words, Judge Chen concluded that the reverse payment itself could not be isolated from other portions of the agreement which, in the

defendants' view, may have been procompetitive and benefitted the generic manufacturer. I agree with Judge Chen and follow his reasoning as to this motion *in limine*.

In sum, the antitrust claims in this case require Purchasers to follow the rule of reason analysis to establish a violation of the antitrust laws. At Step 1, they will have to show there was a payment made by Merck to Glenmark to avoid the risk of competition -- they do this by characterizing the definition of "generic ezetimibe," as illuminated by Defendants' subsequent conduct, as a no-AG provision. At Step 2, Defendants will have to show a procompetitive justification for the Settlement Agreement -- they may do this by claiming, for example, that the settlement allowed for earlier entry than would have been otherwise allowed by the date of the RE'721 patent's expiry. When Defendants offer this and other justifications at Step 2, the burden will shift to Purchasers at Step 3 to rebut those justifications. In doing so, Purchasers may certainly argue that the procompetitive justifications offered are not sufficient because they only bear on the Settlement Agreement as a whole, and not the no-AG provision specifically. In other words, it is entirely proper for Purchasers to point out that an early entry date of December 2016 is anticompetitive because entry would have occurred much earlier but-for the no-AG provision -- which they contend purchased additional delay. But these arguments are presented at Step 3,

when Purchasers must establish that the challenged restraint -- as found by the jury -- was ultimately anticompetitive.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs' motion *in limine* No. 15 (ECF No. 1806, at 2) is DENIED. Objections to specific evidence related to Defendants' claimed procompetitive justifications are reserved for trial.

IT IS SO ORDERED.

/s/   
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Douglas E. Miller  
United States Magistrate Judge

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DOUGLAS E. MILLER,  
UNITED STATES MAGISTRATE JUDGE

April 11, 2023